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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/849,729 05/04/2001 Jen-Kuei Liu RDID0070US 8090

7590 06/27/2003

Kenneth J. Waite Roche Diagnostics Corporation 9115 Hague Road, Bldg. D P.O. Box 50457 Indianapolis, IN 46250-0457 EXAMINER
FOLEY, SHANON A

ART UNIT PAPER NUMBER
1648

DATE MAILED: 06/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/849,729	LIU ET AL.
	Examiner	Art Unit
	Shanon Foley	1648
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>1</u> MONTH(S) FROM		
THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be tir within the statutory minimum of thirty (30) day rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed rs will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).
Status		
1) Responsive to communication(s) filed on <u>04 N</u>	<u>1ay 2001</u> .	
2a) ☐ This action is FINAL . 2b) ☑ Thi	s action is non-final.	• •
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) Claim(s) 1-13 is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6) Claim(s) is/are rejected.		
7) Claim(s) is/are objected to.		
8)⊠ Claim(s) <u>1-13</u> are subject to restriction and/or election requirement. Application Papers		
9)☐ The specification is objected to by the Examiner	·.	
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.		
If approved, corrected drawings are required in reply to this Office action.		
12) The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		·
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a) All b) Some * c) None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 		
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).		
a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)		y (PTO-413) Paper No(s) Patent Application (PTO-152)
		

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 and 2, drawn to an isolated SVII virus, classified in class 435, subclass 235.1.
- II. Claims 3 and 4, drawn to an isolated polynucleotide, classified in class 536, subclass 23.1.
 - If applicant elects this group, applicant is further required to elect one of the following patentably distinct inventions A or B:
- A) a polynucleotide and a complement thereof that hybridizes to the sequence of Figure
- 1. If this group is elected, claim 9 will also be examined.
- B) an isolated polynucleotide and a complement thereof encoding an SVII protein or fragment. If this group is elected, claim 8 will also be examined.
- III. Claims 5-7, drawn to an isolated SVII protein or fragment and a vaccine, classified in class 424, subclass 204.1.
- IV. Claim 10, drawn to an isolated polyclonal antisera that binds to a virus or a viral protein, classified in class 530, subclass 389.4.
- V. Claim 11, drawn to a monoclonal antibody, classified in class 530, subclass 388.3.
- VI. Claim 12, drawn to a method of detecting SVII with an antibody, classified in class 435, subclass 5 and 7.1.
- VII. Claim 13, drawn to a method of detecting SVII with a probe, classified in class 435, subclass 5 and 6.

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The inventions are distinct, each from the other because of the following reasons:

Inventions A and B are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to structurally and functionally distinct polynucleotides. The polynucleotide of group A is required to hybridize to a polynucleotide of Figure 1. A polynucleotide that hybridizes to another is only required to possess at least three nucleotideswhile the polynucleotide of group B is required to encode an SVII protein or a fragment. Neither of the polynucleotides of groups A or B possess the same structural or functional features to perform the required function of the other in the claim. Therefore, each of the polynucleotides are patentably distinct.

Inventions I, II, III, IV, V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise distinct structural characteristics that enable completely different functions for each of the compositions. The virus of group I is able to infect cells and propagate using cellular machinery. The polynucleotides of group II comprise nucleic acids, while the SVII protein comprises amino acid residues. The proteins do not require the polynucleotides to encode them as the polynucleotides and the proteins can each be made synthetically. The antibodies of groups V and VI are different because the antibody of group V is monoclonal and possesses physical structures that allow more specific binding that the polyclonal antisera of

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group IV. Each of the different inventions differ in their physical properties such as chemical structure, primary sequence, molecular weight and are novel and unobvious over each other.

Inventions IV, V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of group IV can be practiced with materially different antibody products of groups IV or V. Alternatively, the antibodies can be used in other hybridization assays or administered to animals to generate other types of antibodies.

Inventions II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method can be practiced with any polynucleotide probe that hybridizes to SVII. Alternatively, the nucleic acid probes can be used in materially different methods, such as binding to PCR-amplified products.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and a divergent subject matter, a search for one group does not include a search for another. Therefore, a restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Feley June 26, 2003